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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,183	06/09/2005	Michael Youngman	PU4963USw	1718

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CORPORATE INTELLECTUAL PROPERTY, MAI B482

FIVE MOORE DR., PO BOX 13398

RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

AULAKH, CHARANJIT

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

09/05/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM

LAURA.M.MCCULLEN@GSK.COM

JULIE.D.MCFALLS@GSK.COM

Office Action Summary

Application No.

10/538,183

Applicant(s)

YOUNGMAN ET AL.

Examiner

Charanjit S. Aulakh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9,10,12,13,15-18,22-26 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22 is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9,10,12,13,15-18,23-26 and 34-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/9/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. According to paper filed on May 15, 2008, the applicants have elected group III without traverse for further prosecution; canceled claims 2, 8, 11, 14, 19-21 and 27-33 and furthermore, have amended claims 1, 3-6, 12, 15-17, 22, 23, 25, 37 and 39.
2. Claims 1, 3-7, 9, 10, 12, 13, 15-18, 22-26 and 34-39 are now pending in the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3-7, 9, 10, 12, 13, 15-18, 23-26 and 34-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following eight different factors (see *Ex parte Foreman*, 230 USPQ at 547; *Wands, In re*, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on atleast

four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, state of the prior art, unpredictability and the breadth of claims.

In regard to lack of enablement issue of instant claims 1, 3-7, 9, 10, 12, 13, 15-18, 23-26 and 34-39 for derivatives (hydrates, solvates or prodrug forms) of instant compounds of formula (I), there is no teaching or guidance present in the specification for preparing any specific hydrates (mono, di, tri or tetra), solvates or prodrugs.

Preparation of specific hydrates or solvates of any compound is a very specialized field and involves their characterization using different techniques such as infrared spectrum, XRD powder diffraction etc. There is no teaching or guidance present in the specification regarding any specific solvents used for preparing specific hydrates or solvates and their characterization using any techniques such as XRD powder diffraction or infrared spectrum etc. There is not even a single example present for preparing any specific hydrate or solvate of instant compounds of formula (I). There is lot of unpredictability regarding stability of different hydrates or solvates of any compound in the art. The instant compounds of formula (I) encompasses hundreds of thousands of compounds based on the values of variables R1, R2, R10, X, d, g and n and therefore, in absence of such teachings, guidance, presence of working examples and unpredictability, it would require undue experimentation to select specific hydrates or solvates of instant compounds with enhanced stability properties.

In regard to prodrug forms, there is no teaching or guidance present in the specification for preparing specific types of prodrug form such carboxylic acid esters, amino acid or

amide esters, phosphate esters, phosphono esters , sulfate esters etc. There is not even a single working example present in the specification for preparing any type of specific prodrug form of instant compounds of formula (I). There is lot of unpredictability in the art for efficacy of different types of prodrug forms of any known compound following their in vivo administration since their efficacy depends upon various factors such as absorption from gut, metabolism by esterases etc. The instant compounds of formula (I) encompasses hundreds of thousands of compounds based on the values of variables R1, R2, R10, X, d, g and n and therefore, in absence of such teachings, guidance, presence of working examples and unpredictability, it would require undue experimentation to select specific types of prodrug forms of instant compounds of formula (I) which will be effective following in vivo administration.

In regard to enablement rejection of claims 23-26 and 37-39 for methods of treatment, the specification mentions that the instant compounds are antagonists of CCR5 receptors in vitro and mentions assay for determining binding at these receptors (see page 76 of specification). However, there is no teaching or guidance present regarding antagonists activity observed with any one of the exemplified compounds. There is no teaching or guidance present in the specification or prior art that hyperactivity of CCR5 receptors is implicated in the etiology of every known viral infection or bacterial infection. There is no teaching in the prior art that structurally closely related compounds having antagonist activity at CCR5 receptors are well known to have therapeutic utility in treating every known viral infection and bacterial infection. There are no working examples present showing efficacy of instant compounds either alone or in combination

with any other drug in known animal models of any viral or bacterial infection. The instant compounds of formula (I) encompasses hundreds of thousands of compounds based on the values of variables R1, R2, R10, X, d, g and n and therefore, in absence of such teachings, guidance, presence of working examples and prior art, it would require undue experimentation to demonstrate efficacy of instant compounds either alone or in combination with hundreds of thousands of other drugs in known animal models of every known viral infection and bacterial infection and hence their utility for treating these disorders.

5. Claims 1, 3-7, 9, 10, 12, 13, 15-18, 23-26 and 34-39 are objected for containing non-elected subject matter.

Allowable Subject Matter

6. The following is a statement of reasons for the indication of allowable subject matter: The instant compounds directed to the elected group (claim 22 is allowed) are allowable over the prior art since they are neither disclosed nor obvious over the prior art. In the art, Kim (WO 2004/009584, cited on applicants form 1449) discloses compounds of formula (I) which are closely related to instant compounds (see page 2, lines 15-30 as well as examples 1-8). However the compounds of Kim differ in structure by having different ring A and furthermore, there is no teaching, suggestion or motivation in the prior art to modify the compounds of kim to prepare the instant compounds.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is

(571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charanjit S. Aulakh/
Primary Examiner, Art Unit 1625